

06 CV 13095

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

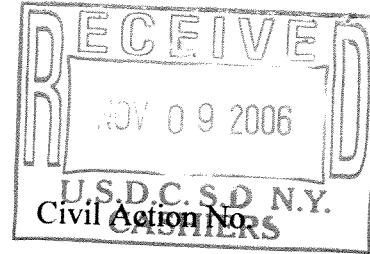
PURDUE PHARMA L.P., THE P.F.
LABORATORIES, INC., and PURDUE
PHARMACEUTICALS L.P.,

Plaintiffs,

v.

MALLINCKRODT INC.,

Defendant.



COMPLAINT

Plaintiffs, Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue"), for their Complaint herein, aver as follows:

Nature of the Action

1. This is an action for a judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

The Parties

2. Plaintiff, Purdue Pharma L.P. ("Purdue Pharma"), is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, Stamford, Connecticut 06901. Purdue Pharma is an owner by assignment of the patents-in-suit identified in paragraph 9 below, and is involved in the manufacture and sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin®, which is listed in the United States Food and Drug Administration's ("FDA")

Approved Drug Products With Therapeutic Equivalence Evaluations, a copy of which is attached hereto as Exhibit A.

3. Plaintiff, The P.F. Laboratories, Inc. ("P.F. Labs"), is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey 07512. P.F. Labs is an owner by assignment of the patents-in-suit identified in paragraph 9 below and is involved in the manufacture and sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

4. Plaintiff, Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals"), is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893. Purdue Pharmaceuticals is an owner by assignment of the patents-in-suit identified in paragraph 9 below and is involved in the manufacture and sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

5. Upon information and belief, defendant, Mallinckrodt Inc. ("Mallinckrodt"), is a corporation organized and existing under the laws of the State of New York, having places of business at 111 Eighth Avenue, New York, New York 10011, and 675 McDonnell Boulevard, PO Box 5840, St. Louis, Missouri 63134. Upon information and belief, Mallinckrodt is currently transacting business in this judicial district by making and shipping, or using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products in this judicial district. Mallinckrodt derives substantial revenue from interstate or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and this judicial district. Mallinckrodt has committed, and

unless enjoined will continue to commit, tortious acts without the State of New York that Mallinckrodt expects or should reasonably expect to have consequences in the State of New York.

Jurisdiction and Venue

6. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Jurisdiction over Mallinckrodt is proper in this Court by virtue of, *inter alia*, defendant's incorporation, place of business, and transaction of business in New York.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

The Patents-in-Suit

9. Plaintiffs, Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in and to the following United States patents, including all right to sue and to recover for past infringement thereof, which patents contain one or more claims covering the composition and method of use of controlled-release oxycodone pain-relief medication:

(a) United States Patent No. 5,549,912, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("912 Patent"), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on August 27, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors;

(b) United States Patent No. 5,508,042, entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("042 Patent"), a copy of which is attached

hereto as Exhibit C, which was duly and legally issued on April 16, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors; and

(c) United States Patent No. 5,656,295, entitled “CONTROLLED RELEASE OXYCODONE COMPOSITIONS” (“295 Patent”), a copy of which is attached hereto as Exhibit D, which was duly and legally issued on August 12, 1997, naming Benjamin Oshlack, Mark Chasin, John J. Minogue, and Robert F. Kaiko as the inventors.

10. On January 5, 2004, the United States District Court for the Southern District of New York (“District Court”) issued an Opinion and Order in *Purdue Pharma L.P. v. Endo Pharms., Inc.*, Civil Action Nos. 00-CV-8029 (SHS), 01-CV-2109 (SHS), and 01-CV-8177 (SHS) (S.D.N.Y.), holding the ’912, ’042, and ’295 Patents (1) infringed by Endo Pharmaceuticals, Inc. (“Endo”) and Endo Pharmaceuticals Holdings Inc. (“Endo Holdings”) and (2) unenforceable due to inequitable conduct (“Endo Unenforceability Order”). Furthermore, the District Court enjoined Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company (collectively, “Purdue Plaintiffs”) from further enforcement of the ’912, ’042, and ’295 Patents (“Endo Injunction”).

11. On January 12, 2004, the Purdue Plaintiffs filed a Notice of Appeal to the Court of Appeals for the Federal Circuit (“Federal Circuit”) seeking, *inter alia*, relief from the Endo Injunction.

12. On January 13, 2004, the Purdue Plaintiffs moved the District Court to suspend the Endo Injunction. On February 17, 2004, the District Court denied that motion.

13. On June 28, 2004, the District Court issued a Memorandum Order in *Purdue Pharma L.P. v. Teva Pharms. USA, Inc.*, Civil Action Nos. 01-CV-8507 (SHS), 01-CV-11212 (SHS), and 03-CV-2312 (SHS) (S.D.N.Y.), granting a motion by Teva Pharmaceuticals

USA, Inc. (“Teva”) for summary judgment of unenforceability of the ’912, ’042, and ’295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order (“Teva Collateral Estoppel Order”).

14. On January 5, 2005, the District Court issued an Order in *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, Civil Action No. 99-CV-3658 (SHS) (S.D.N.Y.), granting a motion by Boehringer Ingelheim GmbH, Roxane Laboratories, Inc., and Boehringer Ingelheim Corp. (“Roxane”) for summary judgment of unenforceability of the ’912, ’042, and ’295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order (“Roxane Collateral Estoppel Order”).

15. On January 5, 2005, the District Court issued an Order in *Purdue Pharma L.P. v. Impax Labs., Inc.*, Civil Action No. 02-CV-2803 (SHS) (S.D.N.Y.), granting a motion by Impax Laboratories, Inc. (“Impax”) for summary judgment of unenforceability of the ’912, ’042, and ’295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order (“Impax Collateral Estoppel Order”).

16. On June 7, 2005, the Federal Circuit issued an Opinion affirming the Endo Unenforceability Order.

17. On February 1, 2006, the Federal Circuit withdrew its June 7, 2005 Opinion and issued a new Opinion (1) affirming the portion of the District Court’s January 5, 2004 Opinion and Order adjudging the ’912, ’042, and ’295 Patents infringed by Endo and Endo Holdings; (2) vacating the Endo Unenforceability Order; and (3) remanding for further proceedings.

18. On March 29, 2006, the District Court entered the mandate from the Federal Circuit’s February 1, 2006 Opinion.

19. On October 3, 2006, the Purdue Plaintiffs and Impax filed a Proposed Stipulated Order with the District Court seeking vacatur of the Impax Collateral Estoppel Order.

20. On October 12, 2006, the District Court vacated the Teva Collateral Estoppel Order in all respects.

21. On October 17, 2006, the Purdue Plaintiffs and Roxane filed a Proposed Stipulated Order with the District Court seeking vacatur of the Roxane Collateral Estoppel Order.

Count for Patent Infringement

22. Plaintiffs incorporate by reference the averments of Paragraphs 1-21 as if set forth herein.

23. To obtain approval to engage in the commercial manufacture, use, or sale of oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, generic versions of Purdue's OxyContin®, before the expiration date of the '912, '042, and '295 Patents, Mallinckrodt submitted to the FDA an Abbreviated New Drug Application ("ANDA"), No. 77-822, pursuant to 21 U.S.C. § 355(j).

24. Upon information and belief, Mallinckrodt filed with ANDA No. 77-822 a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that the '912, '042, and '295 Patents are invalid, unenforceable, or will not be infringed by Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

25. On or about October 4, 2005, Purdue received a letter from Mallinckrodt purporting to be a Notice of Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) ("Notice Letter") informing Purdue of Mallinckrodt's submission of ANDA No. 77-822 and explaining

that the sole basis for its Paragraph IV Certification with respect to the '912, '042, and '295 Patents is the alleged collateral estoppel effect of the Endo Unenforceability Order and the Federal Circuit's June 7, 2005 Opinion affirming the Endo Unenforceability Order.

26. But for the Endo Unenforceability Order and Endo Injunction, the District Court's February 17, 2004 denial of the Purdue Plaintiffs' motion seeking relief therefrom, and the Teva, Roxane, and Impax Collateral Estoppel Orders, Purdue would have been free to bring an action for infringement of the '912, '042, and '295 Patents against Mallinckrodt within 45 days from receipt of the Notice Letter, which would have triggered, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a 30-month stay of FDA approval of Mallinckrodt's ANDA No. 77-822.

27. Upon information and belief, the composition and methods for controlling pain used in Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, as set forth in ANDA 77-822, are claimed in one or more claims of the '912, '042, and '295 Patents.

28. Upon information and belief, Mallinckrodt's ANDA No. 77-822 contains information to show that its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg: (a) are bioequivalent to Purdue's OxyContin®; (b) have the same active ingredient as Purdue's OxyContin®; (c) have the same route of administration, dosage form, and strengths as Purdue's OxyContin®; and (d) have the same, or substantially the same, proposed labeling as Purdue's OxyContin®.

29. Pursuant to 35 U.S.C. § 271(e)(2)(A), Mallinckrodt's submission to the FDA of ANDA No. 77-822 to obtain approval to engage in the commercial manufacture, use, or sale of Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, was an act of infringement of the '912, '042, and '295 Patents.

30. Pursuant to 35 U.S.C. § 271(a), Mallinckrodt's commercial manufacture, use, and sale of its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute direct infringement of the '912, '042, and '295 Patents.

31. Pursuant to 35 U.S.C. § 271(b), Mallinckrodt's commercial manufacture, use, and sale of its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute induced infringement of the '912, '042, and '295 Patents.

32. Pursuant to 35 U.S.C. § 271(c), Mallinckrodt's commercial manufacture, use, and sale of its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute contributory infringement of the '912, '042, and '295 Patents.

33. Upon information and belief, Mallinckrodt has been aware of the existence of the '912, '042, and '295 Patents but nevertheless has been and is now infringing those patents by seeking approval to engage in the commercial manufacture, use, or sale of oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg. This infringement by Mallinckrodt has been and continues to be willful and deliberate and in total disregard for Purdue's lawful rights under the '912, '042, and '295 Patents, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

34. Upon information and belief, Mallinckrodt has been aware of the Federal Circuit's February 1, 2006 Opinion vacating the Endo Unenforceability Order but nevertheless has maintained its Paragraph IV Certification based solely on the alleged collateral estoppel effect of the Endo Unenforceability Order. This conduct by Mallinckrodt renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

35. The acts of infringement by Mallinckrodt set forth above with respect to Mallinckrodt's oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80

mg, will cause Purdue irreparable harm for which they have no adequate remedy at law, including irreparable harm within the State of New York and this judicial district, and will continue unless preliminarily and permanently enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

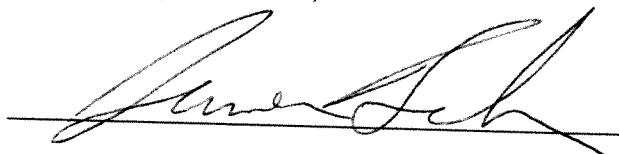
- A. Adjudging that the '912, '042, and '295 Patents are valid and enforceable;
- B. Adjudging that Mallinckrodt has infringed the '912, '042, and '295 Patents and that such infringement has been willful and deliberate;
- C. Ordering Mallinckrodt to amend its Paragraph IV Certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);
- D. Ordering, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mallinckrodt's ANDA No. 77-822 to be a date that is not earlier than 30 months from the date of receipt by Purdue of the Notice Letter;
- E. Ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mallinckrodt's ANDA No. 77-822 to be a date that is not earlier than the last date of expiration of the '912, '042, or '295 Patents;
- F. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Rule 65, Fed. R. Civ. P., Mallinckrodt, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from the commercial manufacture, use, offer to sell, or sale within, or importation into, the United States, of any drug product or active pharmaceutical ingredient that infringes the '912, '042, and '295 Patents;

G. Awarding Plaintiffs damages, together with prejudgment interest and costs, to the full extent provided by 35 U.S.C. §§ 271(e)(4)(C) and 284;

H. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

I. For such other and further relief as the Court may deem proper and just under the circumstances.

Respectfully submitted,



Date: November 9, 2006

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EXHIBIT A

Electronic Orange Book

Approved Drug Products with Therapeutic Equivalence Evaluations

Current through June 2006**

** In order to provide timely consumer information on generic drugs, the Electronic Orange Book will be updated daily as new generic approvals occur.

Refer to [FAQ](#) for additional information. **New!!**

Annual Edition

FAQ

[**Search by Active Ingredient**](#) [**Search by Applicant Holder**](#)

[**Search by Proprietary Name**](#) [**Search by Application Number**](#)

[**Search by Patent**](#)

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Drug questions email: DRUGINFO@CDER.FDA.GOV

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Science
Office of Generic Drugs

Proprietary Name Search Results from "OB_Rx" table for query on "oxycontin."

Appl No	TE Code	RLD Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
020553 AB	No	OXYCODONE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	10MG	OXYCONTIN	PURDUE PHARMA LP
020553 AB	No	OXYCODONE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	20MG	OXYCONTIN	PURDUE PHARMA LP
020553 AB	Yes	OXYCODONE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	40MG	OXYCONTIN	PURDUE PHARMA LP
020553 AB	No	OXYCODONE HYDROCHLORIDE	TABLET, EXTENDED RELEASE; ORAL	80MG	OXYCONTIN	PURDUE PHARMA LP

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through June, 2006

Patent and Generic Drug Product Data Last Updated: July 17, 2006

Search results from the "OB_Rx" table for query on "020553."

Active Ingredient: OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL
Proprietary Name: OXYCONTIN
Applicant: PURDUE PHARMA LP
Strength: 10MG
Application Number: 020553
Product Number: 001
Approval Date: Dec 12, 1995
Reference Listed Drug No
RX/OTC/DISCN: RX
TE Code: **AB**

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL
Proprietary Name: OXYCONTIN
Applicant: PURDUE PHARMA LP
Strength: 20MG
Application Number: 020553
Product Number: 002
Approval Date: Dec 12, 1995
Reference Listed Drug No
RX/OTC/DISCN: RX
TE Code: **AB**

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL
Proprietary Name: OXYCONTIN
Applicant: PURDUE PHARMA LP
Strength: 40MG
Application Number: 020553
Product Number: 003
Approval Date: Dec 12, 1995
Reference Listed Drug Yes
RX/OTC/DISCN: RX
TE Code: **AB**

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL
Proprietary Name: OXYCONTIN
Applicant: PURDUE PHARMA LP
Strength: 80MG

Application Number: 020553
Product Number: 004
Approval Date: Jan 6, 1997
Reference Listed Drug No
RX/OTC/DISCN: RX
TE Code: **AB**
Patent and Exclusivity Info for this product: [View](#)

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Patent and Generic Drug Product Data Last Updated: July 17, 2006

Patent and Exclusivity Search Results from query on Appl No 020553 Product 001 in the OB_Rx list.**Patent Data**

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
020553	001	4861598	AUG 29,2006			
020553	001	4970075	AUG 29,2006			
020553	001	5266331	OCT 26,2007			
020553	001	5508042	APR 16,2013			<u>U-443</u>
020553	001	5549912	OCT 26,2007			
020553	001	5656295	OCT 26,2007			<u>U-443</u>

Exclusivity Data**There is no unexpired exclusivity for this product.**

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.
4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.
5. U.S. Patent Nos. RE36481 and RE36520 are being relisted for Zocor (NDA 19-766) pursuant to the decision and related order in Ranbaxy Labs. v. Leavitt, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents will remain listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act have been triggered and run, unless the agency's appeal of the decision to the U.S. Court of Appeals for the District of Columbia is decided in the agency's favor before the exclusivity periods have expired. While the patents remain listed, any new or pending ANDA referencing Zocor must contain patent certifications to these patents. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046.

[View a list of all patent use codes](#)
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Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through June, 2006

Patent and Generic Drug Product Data Last Updated: July 17, 2006

EXHIBIT B



US005549912A

United States Patent [19]

Oshlack et al.

[11] Patent Number: 5,549,912
 [45] Date of Patent: *Aug. 27, 1996

[54] CONTROLLED RELEASE OXYCODONE COMPOSITIONS

[75] Inventors: Benjamin Oshlack, New York, N.Y.; Mark Chasin, Manalpan, N.J.; John J. Minogue, Mount Vernon, N.Y.; Robert F. Kaiko, Weston, Conn.

[73] Assignee: Euro-Celtique, S.A., Luxembourg, Luxembourg

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,266,331.

[21] Appl. No.: 81,302

[22] PCT Filed: Nov. 25, 1992

[86] PCT No.: PCT/US92/10146

§ 371 Date: Jun. 18, 1993

§ 102(e) Date: Jun. 18, 1993

[87] PCT Pub. No.: WO93/10765

PCT Pub. Date: Jun. 10, 1993

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 800,549, Nov. 27, 1991, Pat. No. 5,266,331.

[51] Int. Cl. 6 A61K 9/22; A61K 9/26

[52] U.S. Cl. 424/468; 424/469; 424/470; 424/486; 424/487; 424/488; 424/494; 424/496; 424/497; 424/498; 424/501; 424/502; 424/495

[58] Field of Search 424/486, 468-470, 424/487-88, 494, 496-498, 464-469

[56] References Cited

U.S. PATENT DOCUMENTS

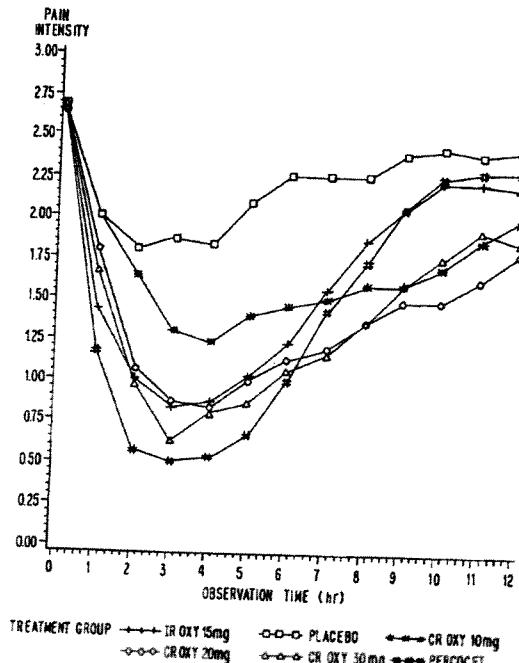
4,861,598 8/1989 Oshlack 424/470
 4,990,341 2/1991 Goldie et al. 424/484

Primary Examiner—Edward J. Webman
 Attorney, Agent, or Firm—Steinberg, Raskin & Davidson, P.C.

[57] ABSTRACT

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions. Another embodiment is directed to a method for substantially reducing the range in daily dosages required to control pain in substantially all patients by administering an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof, such that a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions are achieved. Controlled release oxycodone formulations for achieving the above are also disclosed.

9 Claims, 5 Drawing Sheets



U.S. Patent

Aug. 27, 1996

Sheet 1 of 5

5,549,912

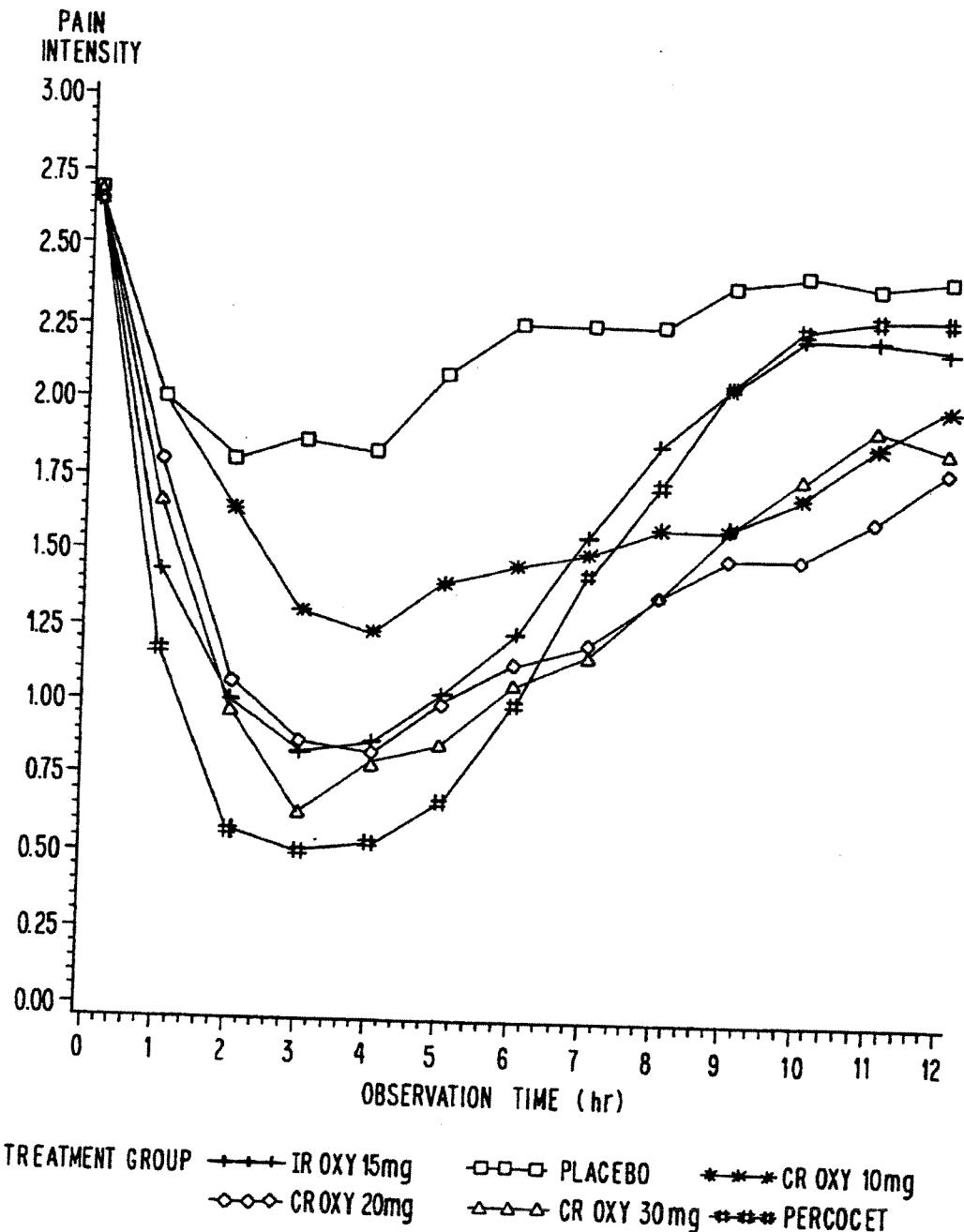


FIG. 1

U.S. Patent

Aug. 27, 1996

Sheet 2 of 5

5,549,912

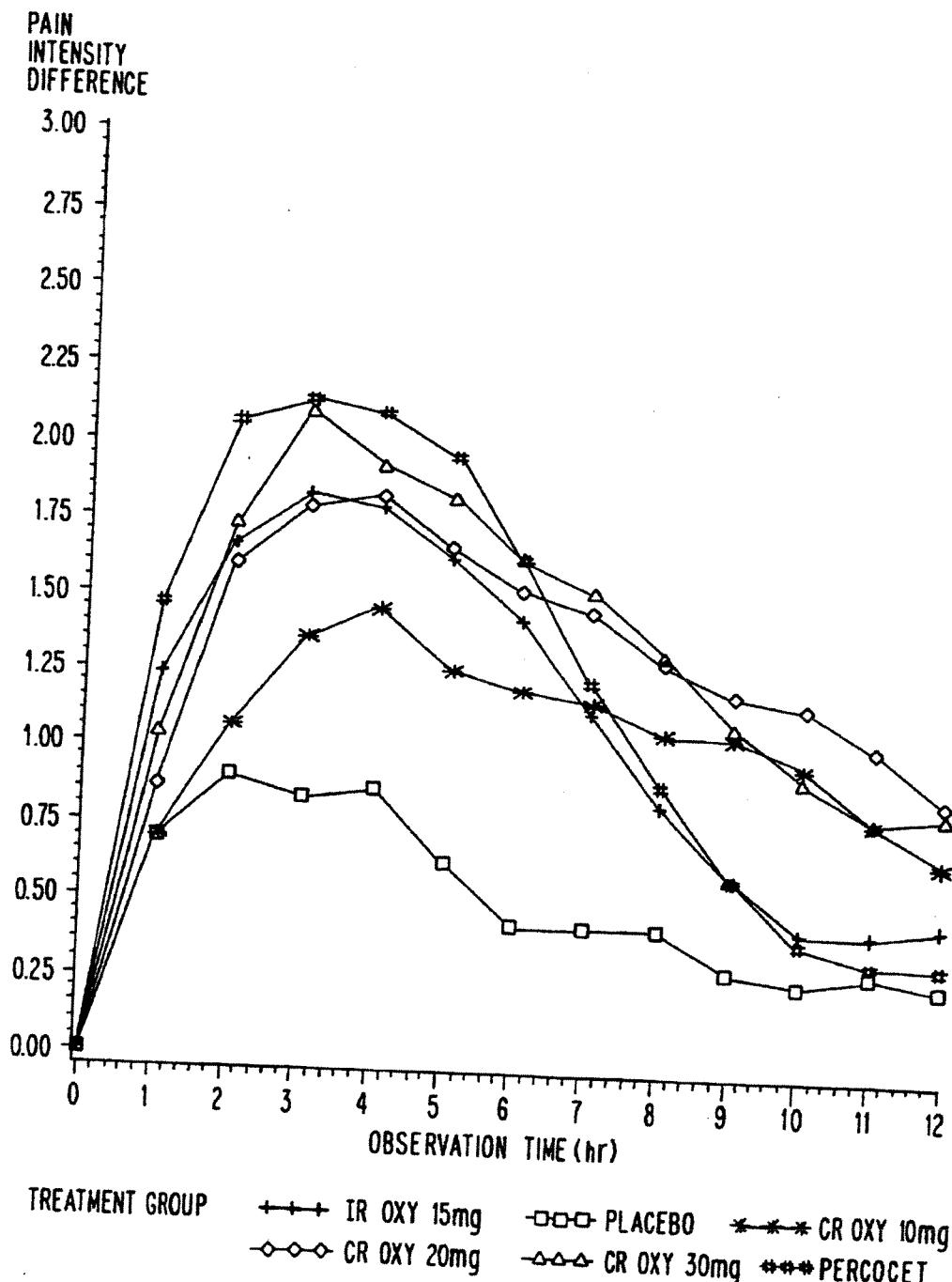


FIG.2

U.S. Patent

Aug. 27, 1996

Sheet 3 of 5

5,549,912

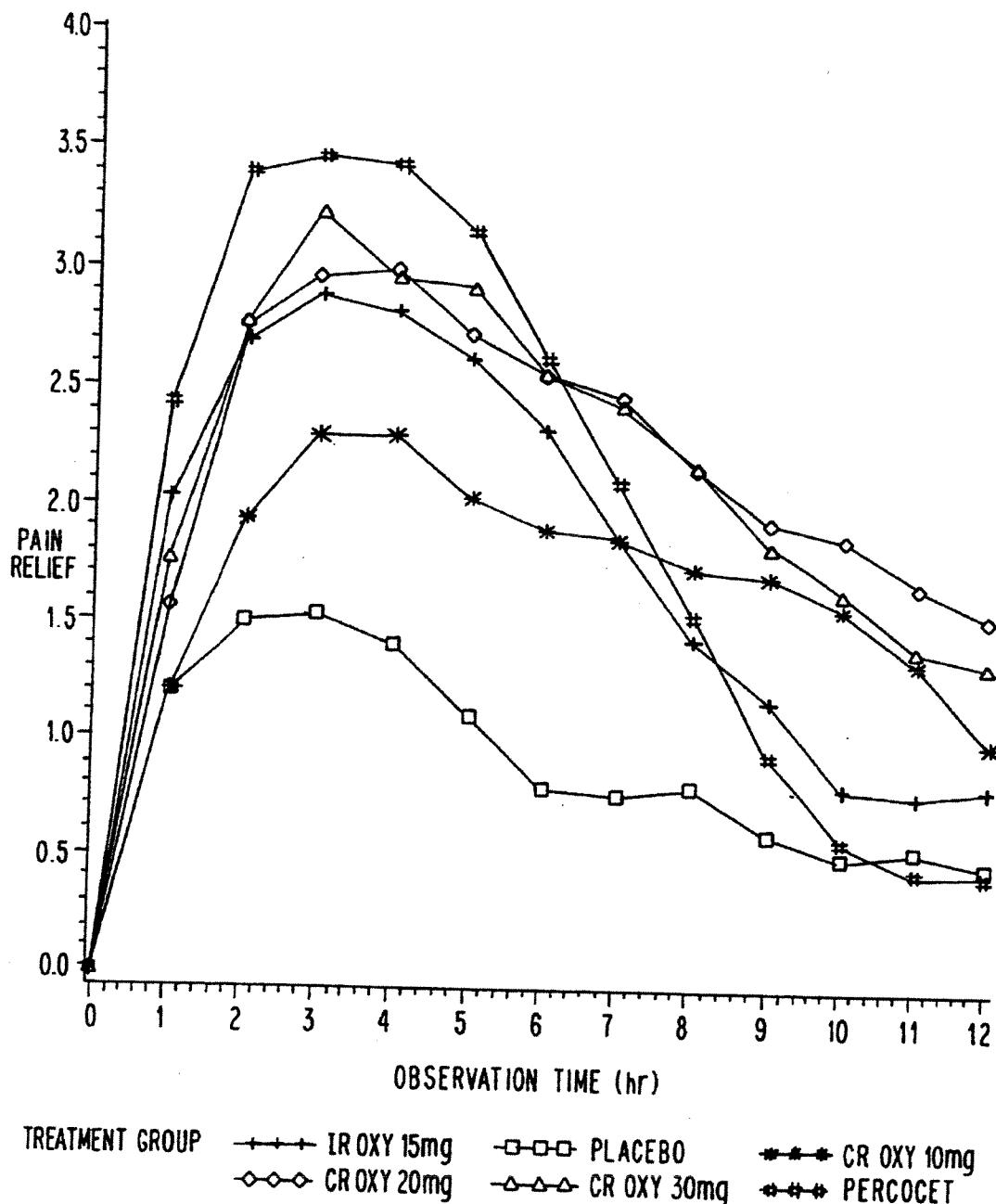


FIG. 3

U.S. Patent

Aug. 27, 1996

Sheet 4 of 5

5,549,912

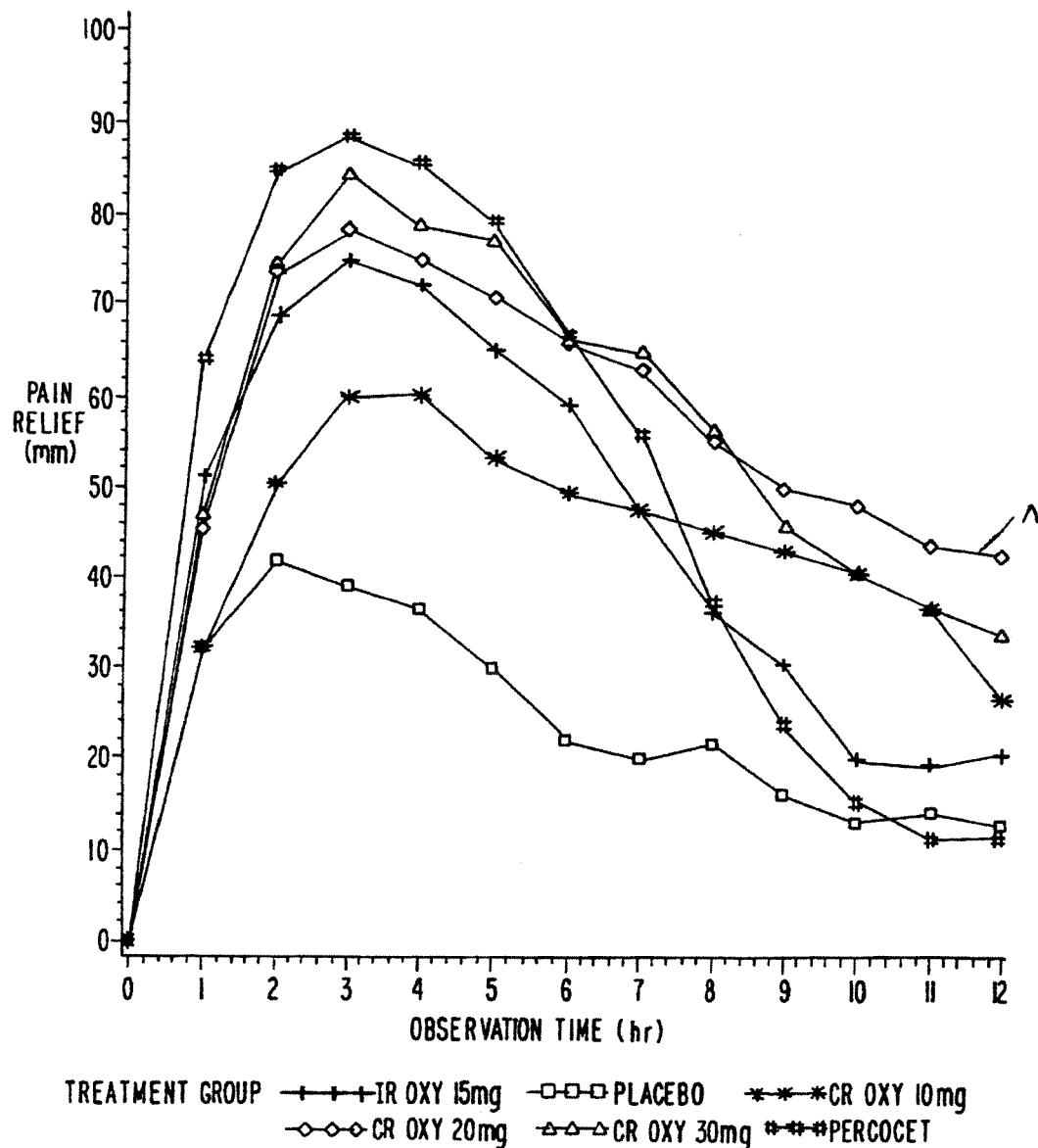


FIG. 4